Remarks

Claims 1, 2, 21, 22, 27, and 28 are pending. Claim 1 is canceled; claims 2, 21, 22, 27 and 28 are amended; new claim 29 is presented.

The new and amended claims are supported throughout the originally filed specification and claims.

Claims 2, 21, and 22 are amended only in their dependency. Claims 27 and 28 were previously dependent from claim 1 and are rewritten in independent form with the cancellation of claim 1.

Claim 27 is supported, e.g., by SEQ ID NO:162 of parent provisional application serial no. 60/427,045, which is identical to residues 10,432-22,152 of SEQ ID NO:5. Claim 27 is also supported, e.g., by SEQ ID NOS:34, 36, and 38 in Tables 14, 16, and 18 of parent provisional patent application serial no. 60/299,380, which are disclosed to be the amino terminal domain, repeat domain, and carboxy terminal domain of CA125 and together make residues 10,432-22,152 of SEQ ID NO:5. Claim 27 is also supported, e.g., by originally filed claims 1, 4, 14, and 15. Originally filed claims 14 and 15 disclose fragments of SEQ ID NO:5 and antibodies that bind to SEQ ID NO:5 and fragments thereof. Claim 27 is also supported by provisional patent application serial no. 60/299,380 as follows. Pages 19-20 of provisional patent application serial no. 60/299,380 discloses recombinant domains and epitopes of CA125 and antibodies against recombinant domains. Pages 6-7 of provisional patent application serial no. 60/299,380 disclose isolated nucleic acids and fragments of the nucleic acids isolated, and expressing isolated nucleic acids from vectors. Page 2, first line of the Summary of provisional patent application serial no. 60/299,380 discloses isolating portions of the CA125 gene. Page 3, lines 5-10 and page 4, line 3 of provisional patent application serial no. 60/299,380 disclose use of recombinant domains, such as individual repeat units, of CA125. Page 3, lines 15-18 of provisional patent application serial no. 60/299,380 disclose recombinant domains of CA125 encompassing epitope binding sites for murine antibodies. There is thus abundant support for isolated nucleic acids used to express fragments of CA125 that can be used to generate antibodies that recognize CA125.

Claim 28 is supported, e.g., by SEQ ID NO:310 of parent provisional patent application serial no. 60/427,045, which is identical to residues 1-10,431 of SEQ ID

NO:5. Claim 28 is also supported, e.g., by originally filed claims 1, 4, 14, and 15, by SEQ ID NO:5, and by paragraphs [0009], [0011], and [0041] of the specification, and by SEQ ID NOS:1 and 4. Paragraph [0009] discloses that the extracellular amino terminal domain is encoded by exons 1-9, as set out in SEQ ID NO:1. It discloses that exon 4 is nucleotides 34575 to 38024 of SEQ ID NO:1. Paragraphs [0011] and [0041] disclose that the amino terminal extension comprises (is encoded by) four genomic exons [exons 1-4 described in paragraph 0009]. A comparison of the sequence of exon 4 (nucleotides 34575-38024 of SEQ ID NO:1) and the cDNA of SEQ ID NO:4 reveals that exon 4 ends at nucleotide 31,485 of SEQ ID NO:4. A comparison of the sequences of exons 1-4 of SEQ ID NO:1, the cDNA sequence of SEQ ID NO:4, and the protein sequence of SEQ ID NO:5 reveals that exons 1-4 encode residues 1-10,427 of SEQ ID NO:5. Claim 21 is supported, e.g., by SEQ ID NO:1 and paragraph [0009]. The element of fragments of SEQ ID NO:5 recognized by an antibody that selectively binds to SEQ ID NO:5 is supported, e.g., by originally filed claim 15, part (d), and claim 14.

Claim 29 is supported, e.g., by SEQ ID NO:4.

Telephonic Conference

Applicants' attorney thanks the Examiner for the courtesy of a telephonic conference between the Applicants' attorney, Hugh McTavish, and the Examiner Peter Reddig. In the conference, it was pointed out to the Examiner that all of the pending claims read on the elected species of SEQ ID NO:4 and therefore it was improper for the Examiner to withdraw the pending claims 21, 22, 27, and 28 from consideration. The Examiner invited the Applicants to submit a response to the Office Action and agreed to examine the pending claims and withdraw the finality of the previous Office Action.

The Rejection of the Claims Under 35 U.S.C. § 102

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Yin and Lloyd (*J. Biol. Chem.*, July 20, 2001, 276:27371-27375). Insofar as this rejection may be applied to present claims 21, 22, and 27-29, this rejection is respectfully traversed.

Claim 27 has a priority date of at least June 19, 2001. Claim 27 is fully supported by provisional patent application 60/299,380, which was filed June 19, 2001. SEQ ID

NOS:34, 36, and 38 in Tables 14, 16, and 18 of parent provisional patent application serial no. 60/299,380 are disclosed to be the amino terminal domain, repeat domain, and carboxy terminal domain of CA125. Together these make up residues 10,432-22,152 of SEQ ID NO:5 as is recited in claim 27. Pages 6-7 of provisional patent application serial no. 60/299,380 disclose isolated nucleic acids and fragments of the nucleic acids isolated, and expressing isolated nucleic acids from vectors. Page 2, first line of the Summary of provisional patent application serial no. 60/299,380 discloses isolating portions of the CA125 gene. Page 3, lines 5-10 and page 4, line 3 of provisional patent application serial no. 60/299,380 discloses use of recombinant domains, such as individual repeat units, of CA125. Page 3, lines 11-18 of provisional patent application serial no. 60/299,380 discloses recombinant domains of CA125 encompassing epitope binding sites for murine antibodies, and use of the recombinant molecules as vaccines or to stimulate patients' immune systems. There is thus abundant support for expressing fragments of CA125 that can be used to generate antibodies that recognize CA125, as is recited in claim 27. The priority date of claim 27 is thus before Yin and Lloyd, and Yin and Lloyd is not prior art to claim 27.

Yin and Lloyd (*J. Biol. Chem.*, July 20, 2001, 276:27371-27375) states that the authors isolated a 5797-base pair sequence containing a stop codon but no clear 5' initiation sequence (abstract). And it is dated July 20, 2001. The alignment the Examiner shows, however, is with Genbank locus AF361486, which is 21,112 bp (not 5797 bp) and states that it was updated on Sept. 8, 2003.

Applicant submits with this response in an Information Disclosure Statement the revision history of AF361486 and AF361486 version 1 GI:14971109. The revision history shows that version GI:14971109 is the earliest version of AF361486 and was submitted on July 20, 2001. In the version submitted on July 20, 2001, AF361486 only had 5797 nucleotides, the same as Yin and Lloyd. The next revision of AF361486 was on Aug. 26, 2003. Version GI:14971109 encodes an 1890-amino-acid protein that is homologous to the carboxy terminal 1890 amino acid residues of the present SEQ ID NO:5 and appears to be the protein sequence disclosed in Yin and Lloyd. The 21,112 bp sequence of the present AF361486 was only submitted on September 8, 2003.

The present application claims priority to U.S. provisional patent application 60/427,045, filed November 15, 2002, before the update of genbank locus AF361486. U.S. provisional patent application 60/427,045 discloses all of SEQ ID NO:5. Table 21 of U.S. provisional application no. 60/427,045 discloses SEQ ID NO:162, which is the sequence of CA125 from residue 10,432 to residue 22,152 of SEQ ID NO:5 of the present application. And Table 25 of U.S. provisional application no. 60/427,045 provides SEQ ID NO:310, which is disclosed to be the amino terminal extension of CA125, residues 1-10,431 of SEQ ID NO:5 of the present application. Table 30 of U.S. provisional application no. 60/427,045 discloses the 66,764-nt cDNA matching SEQ ID NO:4 of the present application and encoding all of SEQ ID NO:5. Accordingly, there is support for all of SEQ ID NO:5 in the present application before the publication date of the updated version of Genbank locus AF361486. Claim 22 of U.S. provisional patent application no. 60/427,045 discloses isolated nucleic acids encoding CA125 and fragments thereof. Claim 24 of U.S. provisional patent application no. 60/427,045 discloses vectors. Claim 28 of U.S. provisional patent application no. 60/427,045 discloses a method of expressing CA125 antigen in a cell involving expressing a nucleic acid encoding a fragment of CA125. Accordingly, all of presently pending claims 2, 21, 22, 28, and 29 are supported by provisional patent application serial no. 60/427,045, filed November 15, 2002, before the update of genbank locus AF361486. Thus, genbank locus AF361486 is not prior art with respect to any of the present claims.

The Yin and Lloyd *J. Biol. Chem.* paper does not disclose the sequence of the nucleic acid isolated. It states that the nucleic acid sequence they found produced a "deduced amino acid sequence of 1890 amino acids (Fig. 3)" (page 27372 second column) and it shows the deduced amino acid sequence in Fig. 3. Alignment of residues 1-100 of the sequence shown in the top portion of Fig. 3 of Yin and Lloyd with the present SEQ ID NO:5 shows imperfect homology with several sequences in the multiple repeat region from residues 12,070 to 21,868 of SEQ ID NO:5. The best homology begins with residue 13721 of SEQ ID NO:5.

Alignment of the sequence beginning with FNFWSS in the middle portion of Fig. 3 with SEQ ID NO:5 produced imperfect homology also with several segments of the

multiple repeat domain of SEQ ID NO:5 between residues 12,070 and 21,868 of SEQ ID NO:5. The best homology begins at residue 15,004 of SEQ ID NO:5.

Alignment of the last line of sequence in Fig. 3, beginning with VLVDGYSPN with SEQ ID NO:5 produced alignment beginning at residues 22,076 of SEQ ID NO:5, in the carboxy terminal domain.

Thus, Yin and Lloyd does not disclose the actual sequence of nucleic acids that the authors discovered. The paper discloses that the nucleic acids encoded the protein sequence shown in Fig. 3. This protein sequence is homologous with segments of the multiple repeat domain and carboxy terminal domain of CA125 (SEQ ID NO:5), which run from amino acid residues 12,070 to 22,152 of SEQ ID NO:5. No homology of the protein sequence disclosed in Fig. 3 of Yin and Lloyd is found with residues 1-10,431 of SEQ ID NO:5. Thus, Yin and Lloyd does not anticipate any of pending claims 2, 21, 22, 28, and 29, because all of these claims recite nucleic acid sequences encoding residues 1-10,431 of SEQ ID NO:5 or a fragment of residues 1-10,431 of SEQ ID NO:5.

Claim 27 is supported by U.S. provisional patent application serial no. 60/299,380, filed June 19, 2001, before Yin and Lloyd (*J. Biol. Chem.*, July 20, 2001, 276:27371-27375). Accordingly, Yin and Lloyd is not prior art with respect to claim 27.

Yin and Lloyd does not disclose any sequence homologous with residues 1-10,431 of SEQ ID NO:5. Claims 2, 21, 22, 28, and 29 all recite nucleic acid sequences encoding residues 1-10,431 of SEQ ID NO:5 or a fragment of residues 1-10,431 of SEQ ID NO:5. Thus, Yin and Lloyd does not anticipate any of claims 2, 21, 22, 28, or 29.

Thus, Yin and Lloyd does not anticipate any of the present claims.

Conclusion

Applicants believe the claims are in condition for allowance, and notification of allowance is respectfully requested. The Examiner is invited to telephone Applicants' attorney (651-207-8270) to facilitate prosecution of this application.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient first class postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this day May 6, 2008.

Hugh McTavish